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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,660	05/30/2007	Hoon Sunwoo	55326.15	2411

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EXAMINER	
WEN, SHARON X	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
08/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,660	SUNWOO ET AL.	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12 and 13* is/are pending in the application.

4a) Of the above claim(s) *12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/10/2007; 06/05/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 04/14/2008, has been entered.

Claims 10 and 11 have been canceled.

Claims 1-9 and 12-13 are currently pending.

Election/Restrictions

2. Applicant's election with traverse of Group I and species, anti-gliadin antibody in Response to Election / Restriction, filed 04/14/2008, is acknowledged. The traversal is on the ground(s) that the Applicants have claimed a composition prepared using a process having a specific sequence of steps and for particular therapeutic use. This is not found persuasive essentially for reasons of record. Regarding the product-by-process limitation for producing the antibody provided by the present claims, is noted that such process does not distinguish from the antibody in the art.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Furthermore, it is noted that the claims provide intended uses for the composition comprising the antibody, but such intended uses do not distinguish from the kit in the art. See e.g. MPEP § 2114.

The requirement is still deemed proper and is therefore made FINAL.

Claims 12-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention/species, there being no allowable generic or linking claim.

Claims 1-8 are currently under examination as they read on a therapeutic composition comprising anti-gluten egg yolk antibodies wherein the specific anti-gluten antibody reads on the elected anti-gliadin antibody.

Priority

3. The domestic priority date for claims 1-8 is deemed the effective filing date of provisional application, USSN 60/521,394, i.e., 04/16/2004.

Information Disclosure Statement

4. Applicant's IDS's, filed 04/10/2007 and 04/10/2007, are acknowledged, and have been considered.

Specification

5. Applicant is requested to review the application for spelling error, the use of trademarks, embedded hyperlinks and/or other form of browser-executable code.

Trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference.

Requirement for Information

6. An issue of public use or on sale activity has been raised in this application. In order for the examiner to properly consider patentability of the claimed invention under 35 U.S.C. 102(b), additional information regarding this issue is required as follows:

Applicant submits that the website describing "Ora Mune Magna" advertises capsules of egg yolk anti-gluten antibody does not provide any indication of how the antibody was prepared in Applicant Arguments/Remarks in response to the Restriction Requriement, filed 04/14/2008 (see page 6, lines 19-20). Given that "Ora Mune Magna" reads on the present invention in that it teaches a composition comprising anti-gluten IgY antibodies (see attached printout for "Ora Mune Magna"), Applicant is required to provide information regarding the "Ora Mune Magna" (e.g., first available date for public use).

Applicant is reminded that failure to fully reply to this requirement for information will result in a holding of abandonment.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-9 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Lee (U.S. Patent 5,367,054, reference of record) in view of Ellis et al. (*Gut* 1998, 43:190-195, reference of record).

The present claims are drawn to a composition comprising anti-gluten IgY antibodies. Ellis et al. teach anti-gluten antibodies that are raised against gliadin, the elected species of anti-gluten antibody, wherein the antibodies are polyclonal and monoclonal IgG antibodies (see entire document, in particular, see page 190, last paragraph on the right column).

The difference between the teaching of Ellis and the present claims is that Ellis's antibodies are not IgY antibodies. However, raising IgY antibodies was a well-known technology in the art at the time of the invention was made as evidenced by Lee (see entire document, in particular, see Background of the Invention). In particular, Lee teaches the process of producing egg yolk antibodies by 1) immunizing the egg-laying fowl with the antigen of interest; 2) collect eggs from the immunized fowl; and 3) prepare the composition from the egg yolk or IgY purified from the egg yolk (see e.g., column 8, lines 7-15, and Figure 1). Moreover, Lee teaches the egg yolk is liquid or dried in the purification process (see Figure 1 and column 3, lines 51-57).

Given that Ellis et al. teach using the anti-gliadin antibody containing composition for immunodetection and the teaching by Lee on the advantage of making IgY antibodies i.e., that egg yolk is a very good source of specific antibodies and that the antibodies are more specific (see column 1, lines 34-46), one of ordinary skill in the art would have been motivated to make the anti-gliadin antibodies for immunodetection as IgY antibodies for the high specificity offered by the egg yolk.

Moreover, ordinary skill in the art would have reasonable expectation of success in making the anti-gliadin IgY antibodies in view of the detailed procedures in making and purifying IgY antibodies outlines in Lee (see e.g., column 8, lines 7-15, and Figure 1) and the detailed disclosure of how to prepared the gliadin antigen taught by Ellis et al. (see page 191, left column).

In view of the composition comprising the anti-gluten antibodies taught by Ellis et al. (see paragraph bridging pages 191-192) and the advantage and practicality in IgY production taught by Lee (see Background of the Invention and Figure 1), it would have been *prima facie* obviate to make an anti-gluten IgY antibody.

Regarding the product-by-process limitation for producing the antibody provided by the present claims, is noted that such process does not distinguish from the antibody in the art.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Furthermore, it is noted that the claims provide intended uses for the composition comprising the antibody (i.e., for treating celiac disease and for oral administration) but such intended uses do not distinguish from the composition in the art. See e.g. MPEP § 2114.

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen, Ph.D./
Examiner, Art Unit 1644
July 15, 2008

/Phillip Gambel/
Phillip Gambel, Ph.D., J.D.
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July 21, 2008